



RECEIVED ON:

OCT 13 2013

EPA Region 10
Office of the Regional Administrator

Via Regular Mail

October 9, 2013

Regional Administrator
United States Environmental Protection Agency – Region 10
1200 6th Avenue
Seattle, WA 98101

Attn: Financial Assurance

RE: FMC Corporation – Pocatello, ID Site IDD 070 929 518
Hazardous Waste Certificate of Liability Insurance
Effective October 1, 2013 to October 1, 2014

Dear Sir or Madam:

Attached please find a revised FMC Corporation – Pocatello, ID Site IDD 070 929 518
Hazardous Waste Certificate of Liability Insurance for the renewal.

Please note AIG is going through a name change from “Chartis” back to “AIG”. The
original documents forwarded included the “new AIG” names. However, it turns out that
AIG did that in error since the new name will not be effective until November.

Thank you.

Cordially,


Cathy Seeman

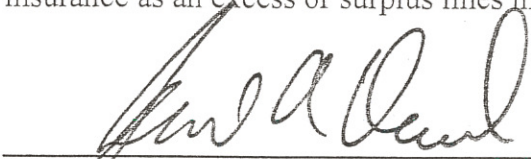
CC: Charles D. Scull
Manager, Insurance
FMC Corporation
1735 Market Street
Philadelphia, PA 19103

Enclosures.

HAZARDOUS WASTE FACILITY CERTIFICATE OF LIABILITY INSURANCE

1. Chartis Specialty Insurance Company, (the "Insurer"), of 175 Water Street, New York, NY 10038 hereby certifies that it has issued liability insurance covering bodily injury and property damage to FMC Corporation, (the "Insured"), of 1735 Market Street, Philadelphia, PA 19103 in connection with the insured's obligation to demonstrate financial responsibility under 40 CFR 264.147 or 265.147. The coverage applies to IDD070929518, FMC Corporation, Phosphorus Chemical Group, Box 4111, Highway 30 West Pocatello, ID 83201 for sudden and nonsudden accidental occurrences. The limits of liability are \$4,000,000 each occurrence and \$8,000,000 annual aggregate for sudden and nonsudden occurrences, exclusive of legal defense costs. The coverage is provided under policy number, 9645384 issued on October 1, 2013. The effective date of said policy is October 1, 2013.
2. The Insurer further certifies the following with respect to the insurance described in Paragraph 1:
 - a. Bankruptcy or insolvency of the insured shall not relieve the Insurer of its obligations under the policy.
 - b. The Insurer is liable for the payment of amounts within any deductible applicable to the policy, with a right of reimbursement by the insured for any such payment made by the Insurer. This provision does not apply with respect to that amount of any deductible for which coverage is demonstrated as specified in 40 CFR 264.147(f) or 265.147(f).
 - c. Whenever requested by a Regional Administrator of the U.S. Environmental Protection Agency (EPA), the Insurer agrees to furnish to the Regional Administrator a signed duplicate original of the policy and all endorsements.
 - d. Cancellation of the insurance, whether by the Insurer or the insured, a parent corporation providing insurance coverage for its subsidiary, or by a firm having an insurable interest in and obtaining liability insurance on behalf of the owner and operator of the hazardous waste management facility, will be effective only upon written notice and only after the expiration of 60 days after a copy of such written notice is received by the Regional Administrator(s) of the EPA Region(s) in which the facility(ies) is (are) located.
 - e. Any other termination of the insurance will be effective only upon written notice and only after the expiration of thirty (30) days after a copy of such written notice is received by the Regional Administrator(s) of the EPA Region(s) in which the facility(ies) is (are) located.

I hereby certify that the wording of this instrument is identical to the wording specified in 40 CFR 264.151(j) as such regulation was constituted on the date first above written, and that the Insurer is licensed to transact the business of insurance, or eligible to provide insurance as an excess or surplus lines insurer, in one or more States.



Joseph Davide
Attorney-in-Fact
Chartis Specialty Insurance Company
175 Water Street
New York, NY 10038

Eng, Sharon

From: Boyd, Andrew
Sent: Thursday, October 17, 2013 7:52 AM
To: Eng, Sharon; Schanilec, Kevin
Subject: FW: SEP 14 - FMC
Attachments: 2013 10 16 SEP 14 letter to EPA and DOJ.pdf

From: Lizanne Davis [<mailto:Lizanne.Davis@fmc.com>]
Sent: Wednesday, October 16, 2013 2:52 PM
To: Robert Forbes; David Heineck; Rosalind Schoof; Bill Bacon; bill bacon; Daniel Stone; Talia T. Martin; susanh@ Boyd, Andrew
Cc: Dominik Alexander; frank Gilliland; Gandy, Jay; Thomas Gesell; Leikin, Jerry; Dorothy Kary; Peter Orris
Subject: SEP 14

Dear All,

Attached is a letter from FMC and the Tribes to EPA/DOJ requesting approval for Phase 2 of the Fort Hall Environmental Health Assessment Study. I will forward the approval when received.

Best,
Liz

Lizanne H. Davis
Director, Government Affairs
FMC Corporation
1050 K Street, NW
Suite 600
Washington, DC 20001

202.956.5211 (Office), 202.412.1055 (Cell)
202.956.5235 (Fax)

lizanne.davis@fmc.com

Sent by United States Mail

October 16, 2013

Chief, Environmental Enforcement Section
Environmental and Natural Resources Division
U.S. Department of Justice
1425 New York Avenue, N.W.
Washington, D.C. 20005

Regional Counsel
Office of Regional Counsel (M/S ORC-158)
U.S. Environmental Protection Agency
1200 Sixth Avenue, Suite 900
Seattle, Washington 98101

Re: United States v. FMC Corporation, No. CIV-98-0406-E-BLW (D. Idaho)
2nd Progress Report under RCRA Consent Decree SEP 14

Dear Sirs:

FMC Corporation (FMC) agreed under the July 13, 1999 Consent Decree in the above-referenced civil action to conduct a set of fourteen Supplemental Environmental Projects (SEPs), including a *Fort Hall Environmental Health Assessment* at the Fort Hall Indian Reservation in southeastern Idaho that is SEP 14 under that decree. One of the SEP 14 requirements was that FMC, following consent decree-specified participation from the SEP 14 Study Management Team (SMT) and Study Design Panel (SDP), submit to the U.S. Environmental Protection Agency (EPA) for approval an Assessment/Study Plan for the health study and the proposed study contractor. That information was submitted to EPA in 2011. In the enclosed letter from EPA dated August, 17, 2011, EPA approved both the Assessment/Study Plan and the contractor selection.

The EPA-approved Study Work Plan calls for the work to be conducted in two phases. These are designated as Phases 1 and 2, with the first phase consisting of determining the feasibility of conducting each of the four planned studies and the second phase consisting of implementation of the studies determined to be feasible. The approved

October 16, 2013
Page 2

contractor Exponent, Inc. began Phase 1 of the study soon after EPA's August 2011 approval.

A second enclosure with this letter is a document prepared by Exponent entitled "2nd Progress Report, Fort Hall Environmental Health Assessment Study," dated August 30, 2013. As discussed in that report, Exponent has completed the Phase 1 feasibility studies. The report describes the work that has been performed during Phase 1, the outcomes of that work, and the range and scope of the studies that have been determined to be feasible in Phase 2. The planned Phase 2 studies are described in the "Methodological and Analytical Path Forward" section of the report. Although these are within the scope of the existing EPA-approved Study Work Plan, both the Tribal and FMC members of the SMT unanimously request that EPA review and approve the Phase 2 studies as set forth in the report. We look forward to prompt EPA approval so that these studies can commence. Thank you.

Sincerely,

William Bacon

William Bacon
General Counsel
Shoshone-Bannock Tribes

Sy DCH

David M. Heineck

David M. Heineck
Summit Law Group, PLLC
Attorney for FMC Corporation

Enclosures (2)
cc with enclosures (by email only)
All SMT members
All SDP members

Eng, Sharon

From: Boyd, Andrew
Sent: Thursday, October 17, 2013 7:51 AM
To: Eng, Sharon; Schanilec, Kevin
Subject: FW: SEP 14 - FMC
Attachments: 2013 10 14 SEP 14 study letter to EPA and DOJ.pdf

From: Lizanne Davis [<mailto:Lizanne.Davis@fmc.com>]
Sent: Wednesday, October 16, 2013 9:42 AM
To: Boyd, Andrew
Subject: SEP 14

Dear Andy,

Wanted to share with you the letter which is pending with Bill Bacon to sign and send to EPA and DOJ regarding Phase 2 of the Study Work Plan. Will advise when it is actually conveyed.

Best,

Liz

Lizanne H. Davis
Director, Government Affairs
FMC Corporation
1050 K Street, NW
Suite 600
Washington, DC 20001

202.956.5211 (Office), 202.412.1055 (Cell)
202.956.5235 (Fax)

lizanne.davis@fmc.com

October 14, 2013

Chief, Environmental Enforcement Section
Environmental and Natural Resources Division
U.S. Department of Justice
1425 New York Avenue, N.W.
Washington, D.C. 20005

Regional Counsel
Office of Regional Counsel (M/S ORC-158)
U.S. Environmental Protection Agency
1200 Sixth Avenue, Suite 900
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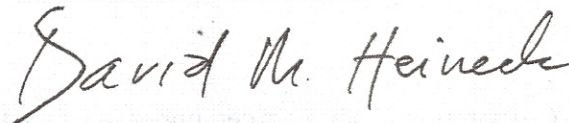
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Sincerely,

William Bacon
General Counsel
Shoshone-Bannock Tribes

A handwritten signature in black ink that reads "David M. Heineck". The signature is written in a cursive style with a large, stylized 'D' and 'H'.

David M. Heineck
Summit Law Group, PLLC
Attorney for FMC Corporation

Enclosures (2)
cc (w/o encl)
All SMT members
All SDP members

RECEIVED

OCT 18 2013

U.S. EPA REGION 10
OFFICE OF REGIONAL COUNSEL

Sent by United States Mail

October 16, 2013

Chief, Environmental Enforcement Section
Environmental and Natural Resources Division
U.S. Department of Justice
1425 New York Avenue, N.W.
Washington, D.C. 20005

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Shoshone-Bannock Tribes

Sy DCH

David M. Heineck

David M. Heineck
Summit Law Group, PLLC
Attorney for FMC Corporation

Enclosures (2)

cc with enclosures (by email only)

All SMT members

All SDP members



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 10

1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

OFFICE OF
COMPLIANCE AND ENFORCEMENT

Reply to: OCE-127

AUG 17 2011

William Bacon
General Counsel
Shoshone-Bannock Tribes
P. O. Box 83203
Fort Hall, Idaho 83203

David Heineck, Esq.
Summit Law Group
315 Fifth Avenue South, Suite 1000
Seattle, Washington 98104-2682

Re: United States of America v. FMC Corporation Consent Decree
Civil No. 98-0406-E-BLW (D. Idaho)
Approval of Fort Hall Environmental Health Assessment Contractor and Assessment/Study Plan

Dear Mr. Bacon and Mr. Heineck:

This is in response to the Assessment/Study Plan and contractor selection information submitted by you, dated August 17, 2011, on behalf of the Fort Hall Environmental Health Assessment Study Management Team. This information was submitted pursuant to Attachment B of the above-referenced Consent Decree, which requires that the Assessment/Study Plan and contractor selection be submitted to EPA for approval. The Assessment/Study Plan and contractor selection is for the Fort Hall Environmental Health Assessment Supplemental Environmental Project, otherwise known as Supplemental Environmental Project No. 14.

EPA has reviewed the information submitted and, for purposes of the Fort Hall Environmental Health Assessment Supplemental Environmental Project, hereby approves the Assessment/Study Plan and contractor selection, dated August 17, 2011, as submitted.

Any technical questions you may have should be directed to Kevin Schanilec of my staff at 206-553-1061. Questions from legal counsel should be directed to Andrew Boyd, Office of Regional Counsel, at 206-553-1222.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward J. Kowalski".

Edward J. Kowalski
Director

The logo for Exponent, featuring the word "Exponent" in a white serif font with a registered trademark symbol, set against a dark, textured background.

Exponent®

2nd Progress Report

Fort Hall Environmental Health
Assessment Study

2nd Progress Report

Fort Hall Environmental Health Assessment Study

Submitted to:

Study Management Team

Prepared by

Dr. Dominik Alexander, PhD, MSPH
Principal Epidemiologist
Exponent, Inc. Health Sciences
Boulder, CO 80303

August 30, 2013

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Background

This draft document provides an updated status report and methodological and analytical path forward to conduct a community health assessment of residents in Fort Hall, Idaho. As described by the Statement of Work in the Request for Proposal for the Fort Hall Environmental Health Assessment Study, the purpose of Phase 1 of this study is to “explore the feasibility of the consultant being able to obtain from existing sources sufficient health data and other information to define the cohort and refine the methodology for conducting the study.” Furthermore, the consultant was directed to “recommend the technically feasible study(ies) that can be conducted within the available project budget.” The stated purpose of Phase 2 is to “Complete the study utilizing the refined methodology developed in Phase 1...”

In accordance with the Project Plan for the Fort Hall Environmental Health Assessment Study, four main tasks were completed as part of Phase 1: 1) review of the Project Portal and other background information; 2) identification and assessment of the study cohort for the four health studies of all-cause mortality, cancer incidence, asthma, and sentinel health outcomes; 3) formulation of the preliminary observations, including a) the cohort, b) environmental data, and c) subject interviews; and 4) recommendation for decision of a detailed study and design of a Phase 2 study. As indicated in the Project Plan, work conducted for Phase 2 will incorporate information reviewed from the Project Portal, and health data and other information ascertained for the purpose of a health analysis among Fort Hall residents. Consistent the approved study design work plan, this study will utilize these information sources and not develop additional environmental sampling data. In addition, and again, consistent with approved study design work plan, Exponent researchers will not collect biological samples, including blood and/or urinary measurement. Exponent will not perform clinical or diagnostic procedures. Rather, Exponent researchers will conduct registry based and chart based data analyses in accordance with the Statement of Work.

We have completed Phase 1 of the research and have moved forward with many of the critical (pre-analysis) components of Phase 2. The following sections describe the steps we have taken in Phase 1 and the suggested directions for Phase 2 that are technically and financially feasible, as well as scientifically justifiable. All of which are under the framework of the agreed upon

Statement of Work. Although we have collected and reviewed hundreds, if not thousands, of documents, reports, and peer-reviewed articles pertaining to Fort Hall, FMC, studies conducted among Native American Populations, and environmental and community health studies among all populations, we have chosen to submit the current progress report as a more task-oriented summary of the methodology and analytical approach to move forward with the conduct of the community health assessment.

General Overview of Completed Tasks

Scientific Foundation

Exponent's epidemiologists and scientists maintain a commitment to objectively conduct a rigorous and well-planned epidemiologic study, and have followed and will continue to follow established and well-utilized scientific methods. The fundamental scientific approach and methodology used by Exponent is consistent with other community health evaluations, and we have conducted an exhaustive review of peer-reviewed literature and public/governmental reports pertaining to conducting research among Native American populations. Each study has unique and intrinsic characteristics, and the Fort Hall community is no different. In fact, evaluating the community health status of Fort Hall residents presents greater challenges due some distinctive aspects of the social and medical infrastructure, socio-demographic dynamics, and within-population variation. Indeed, the Fort Hall reservation is comprised of tribal and non-tribal members, and it is important to examine the health status of all residents. However, it is fundamentally and scientifically necessary to stratify analyses as well to account for the aforementioned demographic distinctions. The primary components of the planned Phase 1 studies involved a comprehensive feasibility assessment to determine the likelihood of being able to conduct certain types of studies. Some key and necessary elements of conducting an epidemiologic study, which ultimately intertwine Phase 1 and Phase 2 tasks, include: clearly communicating the objective and nature of the study to the study-area residents; selection of the study population; selection of the comparison population(s); identifying high quality sources of information for proper assessment of exposure(s), outcomes, and other key variables; proper tracing of study participants over time to mitigate the impact of potential loss to follow-up; and, subsequently ensuring that these critical steps produce high-quality, comprehensive data, for analyses to examine the relationship between the exposures and outcomes of interest in subsequent phases of the project.

Brief Summary of Completed Tasks

Review of the Project Portal and other background information

Exponent health scientists with expertise in exposure assessment and epidemiology reviewed numerous documents in the Project Portal with the purpose of identifying useful information to conduct the four proposed health studies of mortality, cancer incidence, asthma, and sentinel health events. However, the information contained within the Project Portal will not be used in the design of the studies; rather, such information could be used to facilitate interpretation of the data analyses and better understand the risk factors if elevated risks are observed. As indicated, Exponent health scientists reviewed relevant scientific peer-reviewed literature, environmental data collected under EPA regulations, and U.S. census data for the same purpose. The documents in the Project Portal contain some information on past and current residents of the Fort Hall Reservation, their vital status (at the macro level), and relevant environmental and exposure assessment data. However, in isolation, this information cannot be utilized to enumerate a community cohort.

The exposure information in the Project Portal includes sampling data obtained during the CERCLA site investigations, such as air modeling, soil sampling, and water sampling results. Potential exposures of interest identified by documents in the Project Portal include, but are not limited to: radium-226; cadmium; arsenic; lead; hexavalent chromium; polonium 210; particulate matter 10; cadmium; and fluoride. Further, we obtained U.S. census data on demographic, economic, and educational characteristics of residents of the Fort Hall Reservation and Off-Reservation Trust Land in 2006-2010 (based on the annual American Community Survey) and 2010 (based on the decennial census). Although this information cannot be utilized to specifically examine individual level exposures and outcomes, it will be beneficial when interpreting the statistical analyses, that is, to evaluate whether a reported exposure may be associated with an outcome in the event that an excess risk is observed in the Fort Hall community.

Site visits, community discussions, Tribal Council meetings, and participation survey

Three on-site meetings were made by the primary study team with the objectives of:

- Viewing the facility location, environmental landscape, and community infrastructure
- Meeting the tribal leaders and key community members (e.g., Tribal Business Council)
- Visiting key locations, such as the Records and Tribal Health offices

- Assembling background data and information including research on resident/population demographic characteristics, healthcare facilities, and economic status
- Enhancing population feedback, involvement, and participation through several community meetings, question and answer sessions, and public forums

The first visit involved meetings with the study management team to discuss the necessary steps in conducting the feasibility assessment and the information required to carry out the study. In addition, Exponent scientists met with key community members of various tribal departments. The second visit involved on-site presentations to both the Tribal Business Council and the Fort Hall community. The information in the presentation was used to make posters describing the study protocol for the community residents to review. The third visit involved discussing the community health study in an open forum at the Fort Hall High School and the Fort Hall dome room. The purpose of these sessions was to help the residents better understand the nature of the study and to enhance community involvement. In addition, the study was discussed in the Chamber Room of the Tribal Business Council, for which full support was received from the tribal leaders. Importantly, the Tribal Leaders endorsed the study and indicated that they would bolster community participation. Our researchers had the opportunity to directly interact with community members to communicate the importance of the study and to initiate and increase their interest in the study. Of importance, Exponent researchers did not focus on communicating with tribal members over non-tribal members. All community interactions were open to the public, and free for all to attend. Unfortunately, despite our efforts, and efforts of certain tribal leaders and members of the SMT, the community meetings were severely under-attended. The meetings were well-publicized, however, few people attended. There appeared to be considerable disinterest in our research efforts, despite the community being aware of our activities.

Based on information obtained from our site visits, review of the project portal, scientific research efforts, community and SMT correspondence, and because of the lack of meeting attendance, Exponent created (with SMT approval) a Willingness to Participate Survey. This was an anonymous survey to determine whether all (i.e., tribal and non-tribal) residents of the Fort Hall Reservation would be willing to complete a detailed questionnaire and/or participate in interviews, and to release medical information, that would allow the research team to ascertain

important information regarding residential history, diet, medical conditions, and lifestyle. In addition, we used the survey as another method to better understand community interest and involvement. Both methods (the open public forums and the mailed survey) produced the same results – seemingly, a lack of involvement and/or desire to contribute. The Willingness to Participate Survey was a short, non-invasive survey, eliciting data on residential history, food sources, land use, and potential confounders (e.g., smoking history, alcohol intake). However, such detailed individual information is not typically ascertained and utilized in large community studies of cancer and mortality because of logistical limitations, concerns about the validity of collected information, selection bias, and cost. Rather, registry-based community studies are more frequently conducted – these are discussed in the next section.

Prior to dissemination of the survey, Exponent researchers took the necessary steps to go through the formal process of protecting individual's privacy. Indeed, following scientific protocol for evaluating human subjects and in accordance with tribal recommendations, Exponent submitted the required Institutional Review Board (IRB) information to the Northwest Portland Area Indian Health Board. Key Exponent investigators were required under IRB protocol to complete the Collaborative Institutional Training Initiative (CITI), which involved a comprehensive online course on conducting human research with a focus on Native populations. Exponent investigators received an exemption letter from the Portland Area Indian Health Service IRB to submit a "Willingness to Participate" survey to Fort Hall residents. Exponent successfully registered with IRB.net, which is the online IRB document repository for all activities related to conducting studies on human subjects. In addition to obtaining IRB exemption status and SMT approval, the willingness to participate survey was approved by the Fort Hall Business Council. Note: we will be using the same IRB to conduct the formal analyses, and will use additional IRBs if necessary.

The survey has been described in the previous progress report. In brief, the survey consisted of two-pages along with a one-page invitation letter describing the purposes of the survey and the overall Fort Hall Environmental Health Assessment Study. The survey was developed by a team of experienced Exponent epidemiologists in consultation with SMT members. The survey elicited information on overall willingness to participate in the current survey (and, if applicable, reasons for non-participation), tribal status, age, gender, place of residence,

household size, and willingness to answer questions about residential history, diet, food sources, water sources, use of local plants in ceremony, occupation, tobacco smoking, physical activity, alcohol consumption, access to health care, and current health for oneself and one's household members. To maximize participation, the survey was designed to be brief, anonymous, clearly relevant to Fort Hall residents, and easy to return in a pre-paid, pre-addressed envelope included with the survey. We made every effort to make the process as easy as possible (i.e., postage paid and pre-addressed return envelope) for the community members. The SMT developed a flyer describing the overall purpose of the Fort Hall Environmental Health Assessment Study, illustrating the steps in Phase 1, and encouraging residents to "get involved by answering surveys in the mail."

Approximately 3500 surveys were sent via mail, and only 9% were returned with agreement to participate, but not all of these respondents were willing to share all types of information (e.g., medical information, alcohol use, etc.). Our goal was to make an effort to determine how willing community members would be to share personal information with the researchers. Regardless, the optimum design is to conduct registry-based analyses for cancer and mortality, as well as being able to evaluate sentinel cancer and mortality events from these studies. If we identify an excess risk of certain disease outcomes, we can re-visit gathering additional individual-level information, such as length of residential history in the Fort Hall area in context of disease latency, to better understand the specific relationship between possible exposures and the observed outcomes. This could be evaluated on a case-by-case basis (e.g., determining whether residential duration in Fort Hall is consistent with disease induction) or by using a case-control approach. Exponent will not collect additional information directly from each participant nor will Exponent researchers collect biological samples. Rather, additional information will be obtained from the registry (if necessary) and/or from public records or tribal directories (if necessary). Using a registry, we will be able to enumerate the cohort retrospectively with confirmed and validated outcomes with a high-degree of follow-up. This is because of the compulsory reporting structure of cancer cases to the Idaho Cancer Registry and of mortality to the National Death Index. "Population-based" cancer data and national death index data are identified in the registries representing Fort Hall residents, and are compared with external populations, such as neighboring counties, the state of Idaho, the United States, and perhaps more appropriately, other native populations. This type of external comparison analysis will

indicate whether certain types of cancer or causes of death are greater or less than what is expected, and this is a well-accepted and utilized design to evaluate the health status of a community. In the absence of individual-level information (rare for a large community based study), this is the optimum scientific methodology to conduct a community health study.

Cancer, Mortality, and Sentinel Events

Consistent with well-accepted and established research methodology, we have made several contacts with representatives of the Cancer Data Registry of Idaho (CDRI). Specifically, we spoke with the head researcher of the CDRI, Chris Johnson, to discuss the logistics and methodological aspects of analyzing cancer incidence data by health district, i.e., Fort Hall. The CDRI allows for data collection at the aggregate, record, and individual level, including specified parameters of interest. The CDRI will serve as the cancer database to identify cases of cancer among Fort Hall residents after linkage of population parameters. In addition, we spoke with Mr. Johnson about linking residential information with the National Death Index, and he confirmed this was standard practice and that he could perform such a linkage. We discussed comparison populations and the options for utilizing cancer and mortality rates from various databases to fully appreciate any potential relationships. We determined that results from both, the cancer analyses and the mortality analyses, would be examined critically to identify any potential sentinel outcomes.

Childhood Asthma

Given the complexities of evaluating childhood asthma, such as variable case definitions, differing diagnostic practices over time, identifying accurate medical charts and records, enumerating study population without selection bias, and obtaining informed consent, the potential analyses of asthma in the Fort Hall community are not as straightforward as the other studies in the Statement of Work. According to the project plan, the objectives are to determine whether the closure of the FMC plant in 2001 significantly decreased the rate of new-onset asthma and the prevalence of asthma exacerbations among children living on the Fort Hall Reservation, and whether particulate air pollution emitted from the FMC plant increased the risk of new-onset asthma or asthma exacerbations in children. Since we are unable to quantify

specifically the level of particulate matter exposure in each individual, we can evaluate rates of new onset asthma before and after the closure of the FMC plant in 2001. This is not without obvious challenges, however, so we have spent considerable time discussing this study with key members of Indian Health Services and have reviewed extensively the literature on this topic.

Three site visits were conducted by the research team between 2011 and 2012 to assess the extent to which we could identify viable data sources and obtain access to relevant non-clinical records. While much of the descriptive demographic data for the current population of the Fort Hall Reservation can be gathered, using resources from the Department of Public Safety, Land Use Policy Commission, Land Information Services, Enrollment Department, Fort Hall Agency of the Bureau of Indian Affairs, historical data for the period of 1990 to 2005 is more challenging to assemble. Based on discussion with Fort Hall staff and review of some of the sources of records, none of these entities appears to have comprehensive information (e.g., name, gender, address, date of birth, date of death) on both tribal members and non-tribal members during the period of interest. While some of the data could be gathered, the chances that this data would be incomplete and/or not comprehensive appear to be very high.

For more of a clinically-based analysis of asthma, we made visits and had several discussions with staff from the Indian Health Center. Outpatient health care for the residents of the Fort Hall Reservation is, and was during the period of interest, provided at many facilities and by many institutions, which produces more variability. Eligible residents are encouraged to seek care first at the Not-Tsoo Gah-Nee Indian Health Center, which opened in October 1990 and includes Out-patient Clinic, Dental, Pharmacy, Lab, X-ray, Optometry, Podiatry, Audiology and Contract Health Services. Implementation of some administrative and medical electronic records started in 1996 and data are available on more than 6,000 patients, but full electronic medical records have only been implemented since 2006. Many residents of the Fort Hall Reservation, including residents not eligible to use the Health Center and some eligible residents, do not use the Health Center for all of medical services, including for pediatric primary care, for specialty treatment, or for medications. Other outpatient facilities used by Fort Hall Reservation residents for childhood asthma care include Pocatello Children's Clinic and other private pediatricians or family practices in Pocatello, Blackfoot, or Idaho Falls. No inpatient care is provided on the Reservation and residents use the hospitals in Pocatello, Blackfoot, Idaho Falls,

and as far as Salt Lake City, Boise, Portland, Seattle, or Phoenix where the IHS inpatient facility for the region is located. Although medications prescribed by Not-Tsoo Gah-Nee Indian Health Center providers are dispensed free-of-charge to eligible patients, other residents and some eligible patients choose to obtain medications at local pharmacies or by mail using their health insurance or paying out of pocket. Thus, asthma medication information from the Not-Tsoo Gah-Nee Indian Health Center would likely be incomplete and the patterns of use may have varied over time. In terms of insurance data, while medical care and medications are provided free-of-charge to eligible patients at the Not-Tsoo Gah-Nee Indian Health Center, many patients receive care outside of the Reservation, which is covered by their employers' insurance, private insurance, the tribal insurance, Medicare, or Medicaid. Furthermore, some residents change from one payer to another over time or depending on the type of services they need. Thus, comprehensive insurance claims data on Fort Hall Reservation residents are not available.

We also evaluated the feasibility of utilizing other sources of information. For example, we identified the Youth Risk Behavior Surveillance System (YRBSS) -- this system allows for analysis of national, state, and local Youth Risk Behavior Surveillance System (YRBSS) data from 1991 – 2011, including data from middle schools and high schools. In addition, we looked into the related, and more comprehensive, Behavior Risk Factor Surveillance System (BRFSS), which is the world's largest, on-going telephone health survey system that aims to track health conditions and risk behaviors. This surveillance system has been used since 1984 in the U.S. Upon speaking with the BRFSS state coordinator of Idaho, Chris Murphy, we learned that while BRFSS collects information on asthma, the data is limited and primarily restricted to adults for most years, as the questions change annually. Upon further discussion regarding YRBSS and BRFSS, it became evident that data regarding asthma among children and young adults in Fort Hall was extremely limited due to insufficient resources, lack of data, and variable reporting and record keeping.

In an effort to identify alternative or modified approaches to evaluate childhood asthma in Fort Hall, we performed a literature search of asthma epidemiology studies, including 1) Studies in children and adolescents, and 2) Studies in American Indian populations. Based on review of the literature, and given the feasibility within the Fort Hall infrastructure, we determined that the most viable analytical approach would be to perform a clinical chart review for the periods

before and after plant closure in 2001. Based on the results from our participant survey and through discussions with Health Services staff, we determined that the most effective and efficient data collection strategy would be to use a Fort Hall tribal member, preferably a health liaison.

We also investigated the feasibility of determining rates of other diseases, such as lupus and rheumatoid arthritis (RA). These two conditions were brought to our attention through extensive interviews and discussion with the Fort Hall residents. After review of the literature and through our teams' epidemiologic and clinical knowledge, Native American ethnicity is considered a risk factor for the development of RA. In fact, it has been estimated to be almost four times more prevalent among Native Americans compared to Europeans. In addition, many Native Americans carry a high risk epitope, placing them at even greater risk. Similarly, lupus is more frequent among minorities, including Native Americans compared to those of Caucasian descent. As a result, the Lupus Foundation started the National Native American Lupus Project. Thus, without individual-level medical information it would not be possible to evaluate such disease conditions.

Methodological and Analytical Path Forward

Researchers attempting to evaluate the health of a community are faced with numerous challenges, such as fully enumerating a cohort population within scientifically relevant demarcated geographical boundaries, obtaining consent from willing study participants, and validating cases of disease. Indeed, researchers assessing the health of a Native American population are faced with the same challenges in addition to potential obstacles pertaining to cultural sensitivities, researcher trust, community involvement, record keeping, and ascertainment of validated medical information. The medical literature indicates that many Native American populations typically have a distinct constellation of lifestyle, cultural, and genetic factors that differentially affect morbidity and mortality rates of various diseases compared with background rates of risk factors and health outcomes in the general population (Cobb and Paisano 1998; Galloway 2005). In addition, Many Native American tribes living in rural areas do not seek routine medical care, making it extremely difficult to evaluate the occurrence of adverse health effects. Because of these inherent challenges, we conducted an in-depth literature review to explore the methodological practices employed by previous investigators. More specifically, we reviewed a series of community health studies conducted among Native Americans residing in various geographical regions in which the health outcomes assessed included cancer, cardiovascular disease, substance abuse, cognitive impairment, and asthma, among others.

Depending on the outcome of interest and scope of the study, the methods used to collect data varied greatly (e.g., utilization of health care records, participatory questionnaires, in-person interviews, health databases such as state cancer registries, the Surveillance Epidemiology and End Results program, and the National Death Index). Upon exploring the various non-registry resources used to collect data, there were several limitations due to sub-optimal participation rates, small population size, and lack of consistent and validated cases reporting. In the case of registry studies, selection of an appropriate comparison population is of concern (note: this is something that we will address in our analyses).

In 2001, the National Cancer Institute funded three centers (and one coordinating center) to test the feasibility of establishing a cohort of American Indian (AI) and Alaska Native (AN) people.

The cohort was named “EARTH” by participating tribal organizations. We acknowledge this cohort here because it serves as a prime example of the monumental undertaking (e.g., an extremely large number of governmental researchers, technical and logistical resources, and grant funding) it is to conduct such an evaluation. Three grants were funded in phase I of the EARTH study, totaling approximately \$6,000,000. Their 4-year proposal focused on the development of an AI/AN cohort to obtain a better understanding of the disparity in disease rates and risk factor knowledge that exist between AI/ANs and U.S. white populations. Note: it appears that virtually all publications from the EARTH project have focused on social characteristics, lifestyle factors, and risk factors. We are not aware of any published analytical studies from this cohort that examined the association between risk factors and cancer, cardiovascular disease, mortality, or other disease outcomes (aside from a few self-reported health outcomes). This is rather disappointing as such a large study could serve as a useful tool for methodological design and could be used as a comparison of results. At any rate, an objective of the AI/AN cohort is to determine how diet, physical activity, and other lifestyle and cultural factors relate to the development and progression of chronic diseases such as cancer, cardiovascular disease, stroke, Type 2 diabetes, chronic lung and respiratory diseases, and related mortality from these diseases. To our knowledge, their proposed objective did not include an environmental or occupational component. It is clear that our study plan cannot replicate the methods of the EARTH cohort (for example, they obtained biological samples from study subjects), however, we will be contacting their principal investigator to determine whether we can use their cancer and mortality rate information (if this type of information is available) for another comparison group (see next section for discussion on analytical comparison groups).

In a registry-based study, individuals in a defined study population (in this case, current and former residents of the Fort Hall Reservation, including tribal and non-tribal members) are linked to an existing disease registry to determine which members of the population have been diagnosed with the disease of interest. Likewise, individuals in a study population can be linked to an existing mortality registry to determine which members of the population have died and, for deceased individuals, what caused their death. Linkages between individuals and registries are performed based on several personal identifiers, such as birth date, Social Security Number, first and last name, maiden name (if applicable), gender, residential address, and date of

diagnosis or death. Once a linkage has been performed, an investigator can calculate the rate of newly diagnosed disease (called the incidence rate) or the mortality rate in the study population by dividing the number of linked cases or deaths, respectively, by the amount of time spent at risk by the entire study population. More specifically, such analyses generate standardized incidence ratios (SIRs) and standardized mortality ratios (SMRs) that are used to compare the overall and cause-specific mortality rate of one study area (e.g., all Fort Hall residents) against a reference population (e.g., comparison with other tribal populations, neighboring counties, etc.). Standardized incidence and mortality ratios are estimates of relative risk. The observed number of deaths in the study and comparison areas can be obtained from Idaho vital statistics data, the National Death Index (NDI), and other databases. Cancer incidence from Fort Hall and statewide comparison areas can be obtained from the Idaho Cancer Registry. The overall population and the age-sex or age-sex-race composition of the study and comparison areas can be extracted from US Census and intra-census estimates, and population estimates from the state of Idaho through the Cancer registry and the NDI.

Analytically, the indirect standardization method is used to estimate SIRs and SMRs comparing the observed number of cases/deaths in the study area to the expected number of deaths for the same area based on the applied cancer incidence/mortality rate from the comparison area. The expected number of cases/deaths is calculated using age- and sex-specific incidence/mortality rates from the reference population and are then applied to the person-years from the study area. For SIR/SMR analyses, the expected number of cases/deaths is calculated as follows:

$$Expected = \sum_{ij} R_{ij} \times PY_{ij}$$

where R_{ij} is the mortality rate for the i^{th} five-year age group and j^{th} sex group in the reference area, and PY_{ij} is the corresponding age- and sex-specific person-years in Fort Hall. If race is also considered, then the index will include another subscript " k " for race. The SIR/SMR is defined as the ratio between the observed number of cases/deaths in Fort Hall and the expected number of cases/deaths. This type of analysis is commonly conducted in community health assessments, and occupational and environmental studies. It is a scientifically rigorous design and is well-supported by the Statement of Work and project plan.

As discussed in the introductory paragraph of this section, the scientific literature indicates that Native American populations commonly have a distinct set of lifestyle, cultural, dietary, and clinical characteristics. Thus, it is crucial that analyses are conducted to attempt to account for the within-culture characteristics. Statistical analyses will be generated to evaluate all Fort Hall tribal and non-tribal residents (as a group), and importantly, analyses will be stratified to evaluate the health status of Shoshone Bannock tribal members. The reason for this is that combining different populations in an analysis is likely to produce heterogeneity in the evaluation of different demographic groups. The most informative, and scientifically and clinically relevant, analyses will be based on the population-specific sub-groups. As mentioned, comparisons will be made with neighboring counties and the entire state of Idaho (i.e. the health status of *all* Fort Hall residents will be compared with the health status of adjacent counties as well as the rate data from Idaho). Additionally, in an effort to account for population heterogeneity, the health status of only Shoshone Bannock tribal members will be compared to national Native American population rates. It is recognized that heterogeneity exists within Native American populations, including Shoshone Bannock tribal members, however, this demographic-specific analysis is necessary to increase the study validity and to interpret the forthcoming analyses.

The study of asthma would involve using tribal members from Indian Health Services or a related department to review medical charts and abstract data for the study periods of interest. For example, we would restrict analysis to patients with records from Indian Health Services, and we would use a records-based approach to identify new onset asthma cases before and after 2001, the year of plant closure. These cases would serve as the numerator and the denominator would be generated by identifying the number of new records in each time period. This would allow us to make relative rate comparisons before and after the closure of the plant. The analysis would be restricted to data from Fort Hall Indian Health Services, and would only cover tribal members affiliated with and/or utilizing the clinic. Given the extreme variability of medical record distribution among all residents, the infeasibility of systematically being able to collect relevant information from clinics outside of Fort Hall, and the differing clinical and diagnostic practices over time, our research efforts will focus on data originating from the Not-Tsoo Gah-Nee Indian Health Center. This feasible research approach will facilitate a review of rates of childhood asthma prior to plant closing vs. post-closing. By focusing on the Fort Hall

clinic, we will be able to enumerate the Shoshone Bannock tribal population who may seek care here. Although it is acknowledged that all (tribal and non-tribal) residents, and even some Shoshone Bannock tribal residents, may not be captured by solely using patients from this clinic, the clinical population serves as a scientifically justifiable and feasible data source that represents the onset of asthma on the Fort Hall reservation. Furthermore, we are not aware of any scientific reason to suggest that the occurrence (or factors contributing to the onset) of asthma may differ between the Not-Tsoo Gah-Nee Indian Health Center patients vs. patients seeking care elsewhere.

[note: italicized text is from the statement of work]

Cancer Incidence Study – *This study is planned to assess the cancer experience of the Fort Hall Reservation population that had potential exposure from FMC releases from 1949 through 2001 as a result of that exposure, to the cancer incidence of non-exposed controls. Work with local health providers and agencies to identify and access cancer incidence data. This would include clinical records, cancer registry data, National Death Index, state, local and tribal information and health data as is pertinent to the study.*

- According to the project plan we have followed this proposed plan of action and will continue to do so with our forthcoming analyses. As indicated, Exponent researchers will be analyzing clinical information from the cancer registry and National Death Index for tribal, local, and state residents.

All-Cause Mortality Study – *This study is planned to compare the mortality experience of the Fort Hall Reservation population that had potential exposure from FMC releases from 1949 through 2001 as a result of that exposure to the mortality experience of non-exposed controls. Bidder shall assess the federal and local mortality data, the National Death Index, and other state, local and tribal sources. It is expected that the mortality data of the tribes would be analyzed utilizing standard epidemiological methods for comparison to other populations.*

- As with the cancer incidence study listed above, we have followed the proposed plan of action and will continue to do so with our forthcoming analyses. As

indicated, Exponent researchers will be analyzing local mortality data among tribal, local, and state residents using the National Death Index.

Childhood Asthma – *To determine whether particulate releases from the FMC plant contributed to the development of new onset asthma or asthma exacerbations in children residing on the Fort Hall Reservation. This study references PM (10 and/or 2.5) and other pollutants that may be identified by the consultant as having been emitted from FMC that are known or possible contributors to asthma etiology. Asthma is a major clinical and public health issue. There is extensive evidence that hospitalization and exacerbations are related to PM exposures. The effects of PM on new onset asthma have yet to be defined. PM exposures from the FMC facility may have had the potential to have contributed to the risk of new onset asthma and asthma exacerbations among Fort Hall children. It is possible that exposure varied among children residing in different areas of the Reservation. **The plant closure in 2001 offers an opportunity to contrast risk for cohorts of children born before and after plant closure.** Pertinent information and health data shall be obtained through personal contacts (interviews, questionnaires, etc.) of incidence in the study group.*

- We will compare rates of new onset within the Fort Hall Indian Health Services clinic before and after plant closure. The most effective course of action will be to use a tribal member(s) in health services to conduct the chart abstraction. As indicated, Exponent researchers will be evaluating the prevalence of asthma before and after plant closure.

Sentinel Health Events – *Health consequences of chronic environmental exposures can be manifested in a variety of ways that make it difficult to determine a precise association. However, there exist a limited number of disease states whose occurrence serves as a biologic marker of such environmental exposures. Develop a list of potential sentinel health events (SHEs) relevant to the Fort Hall Reservation population, **collect information on the prevalence of each potential SHE from all known clinical databases, compare the prevalence rates to expected rates.** Accuracy and validity of the health data and information must be verified as appropriate for study area use and application.*

- We have reviewed the literature and have discussed certain outcomes with community residents. As discussed in this document, we will conduct the cancer and mortality analyses and based on the results from these studies, determine whether any possible sentinel health outcomes exist. If we (and with consult from the SDP) identify any outcomes that may be classifiable as a sentinel event, we will examine further the underlying risk factors for such cases. As indicated, Exponent researchers will compare the observed rates of sentinel cancer and mortality outcomes with the expected rates.

We are now ready to move forward with the essential and necessary steps to conduct the analytical phase of the studies. We have listed the next methodological and analytical steps to proceed with gathering the data, identifying the relevant comparison groups, and determining the appropriate statistical procedures.

Methodological and Analytical Steps:

- Final consensus from SDP to move forward with the analytical phase of the study designs (Note: it is essential that we begin to move forward with at least two of the studies even if not all have reached consensus. Notably, it is crucial that we begin work on the cancer study and mortality study, which will lead into the sentinel events assessment.) [*update: the SDP has given their consensus to move forward*]
- Obtain IRB approval from Northwest Portland Area Indian Health Board. Note: we have already registered with this IRB, and received prior approval for the survey. In the unlikely event that this IRB will not cover all aspects of the study, we will use another IRB (the utilization of another IRB is commonplace).
- Cancer: Speak with Velda Racehorse from Fort Hall records to submit population database information to Chris Johnson from the Idaho Cancer Registry. Work with Mr. Johnson and other staff members from the Registry to identify the cancer types of interest, variable coding, years of interest, and other analytical parameters. We plan to gather rate data for all types of cancer, and we expect that some cancers will be combined to form relevant groupings.

- Mortality: Similar process as above. Chris Johnson will work on the linkage between the population database and the National Death Index. All reportable causes of death will be recorded and analyzed as deemed appropriate.
- Cancer and Mortality: Identification of comparison populations. These populations will be used to calculate expected counts of cancer and causes of death. The observed cases and deaths in Fort Hall will be compared with the expected number of cases and deaths derived from these comparison populations. To account for the demographic, geographical, and cultural variability between the Fort Hall community and the other population groups, a minimum of three referent populations will be used (see comments above). The first comparison will be based on rates from neighboring counties in Idaho, the second will be based on the entire state of Idaho, and the third will be based on a representative Native American population.
- The cancer and all-cause mortality statistical analysis will be conducted after obtaining the Fort Hall cancer and mortality database file from the Registry and the rates from the comparison populations. Standardized incidence ratios will be calculated for cancer and standardized mortality ratios will be calculated for all deaths (as discussed above).
- We will then interpret the analyses based on the observed associations. The importance of using multiple comparison groups is that it will allow us to evaluate consistency of associations given the complex study population of interest. Thus, if we observe a positive association for a certain type of cancer when using the state comparison group, we can determine if that observation is substantiated by the associations in the regional county and Native American referent populations.
- Sentinel events: After we complete the cancer incidence and all-cause mortality analysis, we will then determine if there are any sentinel outcomes (rare types of cancer or causes of death) that occur at a considerably greater rate than expected. We will be able to identify a rare (or unexpected) outcome based on the expected counts using our three referent populations. If, in the event that we observe an excess of a rare outcome, we will then investigate possible reasons for the rare occurrence. We will consult with the SDP to discuss whether the possible sentinel event warrants investigating further or if the outcome would be in concert with the perceived health events in a Native American population. In addition, we may deem it necessary to conduct a case-control analysis to

further identify any potential risk factors that may contribute to the higher than expected rate of cancer or mortality. For example, if 0.8 cases of a rare type of bone cancer are expected, and we observe 13 cases on the Fort Hall community, this would constitute a possible sentinel event. We would then explore options to better understand the occurrence of this rare malignancy, such as conducting a case-control analysis or determining whether residence duration in the Fort Hall area is consistent with the expected cancer latency period.

- Asthma: we will consult with Indian Health Services to identify liaisons to abstract relevant information from medical charts. Exponent staff will not directly review records of patients in accordance with protecting the privacy of individuals. Rather, we will sub-contract tribal members with experience in medical records to conduct all data abstraction. This information will then be de-identified and assembled in a database to be used for analytical purposes.
- Exponent epidemiologists and clinicians will interview and consult with tribal liaisons to create a methodological data abstraction protocol with comprehensive variable coding. Importantly, we will create a comprehensive data abstraction spreadsheet for the collection of relevant clinical, lifestyle, and demographic information.
- Statistical analyses comparing the occurrence of asthma before and after the FMC plant closure in 2001 will be generated. Analyses will be conducted by Exponent statisticians and the results will be interpreted by our epidemiologists and clinicians.
- The results of all above analyses will be summarized in tabular, graphical, and report format with corresponding interpretation, strengths, and limitations. We propose giving separate in-person or WebEx presentations to both the SDP and SMT. Following discussion of study results, we will write a formal report of the study results.

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